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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,431	03/28/2002	Kakuji Tojo	13357.4USWO	6928

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EXAMINER	
YOUNG, MICAH PAUL	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,431	TOJO ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Response and Amendment filed 3/11/04.

Claim Rejections - 35 USC § 102

1. The rejections over Hille et al, Miranda et al and Deurer et al have been withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Deurer et al (USPN 5,869, 086 hereafter '086), Godbey (USPN 6,086,911 hereafter '911) and Fukiage et al (EP 0 771 565 hereafter '565). Claims 1-3, and 6 are drawn to an ophthalmic transdermal patch comprising a drug and penetration enhancers. Claims 11-13, and 16 are drawn to a method of treating a disease of the eye using the patch of the invention. Claims 4 – 5, and 7 recite specific concentration of the transdermal components. Claims 11 – 20 recite a method for the treatment of a disease of the eye. The treatment comprises applying the transdermal patch of claims 1 – 10. Claims 14 – 15 and 17 recite specific concentrations of the transdermal components.

'086 et al discloses a transdermal patch for the treatment of glaucoma. The patch comprises an active agent that can treat the disease of the eye. The patch comprises an acrylic

polymer based matrix, which further comprises penetration enhancers such as isopropyl myristate an oleyl alcohol. The patch was administers to patients for the treatment of the disease (col. 3, lin. 38 – 60; col. 4, lin. 22 – 25; examples). What is lacking in this reference is a disclosure of polyoxyethylene oleyl ethers as possible penetration enhancers.

The'911 patent discloses a transdermal matrix formulation comprising a matrix, backing sheet and various penetration enhancers (col. 4, lin. 38 – 58). The penetration enhancers include fatty acid esters such as isopropyl myristate and polyoxyethylene oleyl ethers 2 and 10 (col. 6, lin. 28 – 53). It would have been obvious to a skilled artisan to combine the enhancers of '911 with the formulation of '086 in order to improve the transmission of active agents across the mucosa.

What is lacking in the references is a teaching of the N-(4-fluorophenylsulfonyl)-L-valyl-L-leucinal drug recited in claims 9, 10, 19 and 20. This ophthalmic drug and its salts are well known in the art and have been disclosed by '565. The '565 patent discloses that the drug can be useful in treating disorders eye, specifically the retina, and also discloses that transdermal delivery is possible (Abstract; pg. 2, lin. 49 – 52; formula (VI), pg. 4; pg. 13, lin. 45 – 50; pg. 38, lin. 2 – 11).

With regard to the claims 4, 5, 7, 14, 15, and 17, which recite specific ranges and concentrations of the penetration enhancers and polymer ratios, it is the position of the examiner that such recitations are non-critical to the patentability of the invention. Applicant is reminded that it has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredients. However, the preparation of various transdermal compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With these things in mind it would have been obvious to a skilled artisan to combine the penetration enhancers of '911 with the formulation of '086 in order to improve the transmission of active agents across the mucosa membrane. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. *See* In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). A skilled artisan would have been further motivated to substitute the active agent of '565 into the transdermal patch combination of '086 and '911 in order to treat disorders of the eye, along with possibly Alzheimer's symptoms. It would have been obvious to combine these teachings and optimize their concentrations with an expected result of an ophthalmic transdermal patch that was useful in treating diseases of the eye.

Response to Arguments

3. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1615

MPY

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600